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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/567,061	02/03/2006	Francisco Javier Vila Pahi	Q92724	9539

23373 7590 04/22/2008

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EXAMINER
HENRY, MICHAEL C

ART UNIT	PAPER NUMBER
1623	

MAIL DATE	DELIVERY MODE
04/22/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/567,061	VILA PAHI ET AL.	
	Examiner	Art Unit	
	MICHAEL C. HENRY	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 January 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *10-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The following office action is a responsive to the Amendment filed, 01/15/08.

The amendment filed 01/15/08 affects the application, 10/567,061 as follows:

1. Claim 10 has been amended. The applicant's amendments have overcome the rejections made under 35 USC § 112, 1st and 112, 2nd in the prior office action mailed 09/17/07. However, the 103 rejection are maintained.
2. The responsive to applicants' arguments is contained herein below.

Claims 10-18 are pending in the application

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Olsen et al. (WO 01/83707 A2).

In claim 10, applicant claims a method of treatment of psoriasis in a mammal, comprising administering to a mammal in need thereof an effective amount of an alkaline or alkaline earth metal chondroitin sulfate obtained from enzymatic hydrolysis of animal cartilage. Claims 11-18 are drawn to said method wherein the said chondroitin sulfate is obtained from a specific source, it is sodium chondroitin sulfate, it is of specific molecular weight range, specific sulfur content and wherein the administration is by specific routes.

Olsen et al. disclose that psoriasis in a mammal (human or animal) can be treated by administering to said mammal chondroitin sulfate (see claims 47 and 49; see also claims 1-5). Olsen et al. disclose that the chondroitin sulfate can be obtained from animal cartilage (see claims 2 and 5). It should be noted that the source of the chondroitin sulfate does not further limit the chondroitin sulfate used.

The difference between applicant's claimed method and the method suggested by Olsen et al. is that applicant uses an alkaline or alkaline earth metal chondroitin sulfate. However, Olsen et al. suggest that a pharmaceutically acceptable salt (which includes alkaline or alkaline earth metal salts such as the common sodium metal salt) can be used (page 18, lines 16-21). In addition, it should be noted that the applicant's also disclose that the chondroitin sulphate (chondroitin sulfate) that is commonly used in therapy is in the form of sodium salt (see page 3, lines 31-32 of applicant's specification).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made to have used the method suggested by Olsen et al. to administer a pharmaceutically acceptable salt of chondroitin sulfate such as sodium chondroitin sulfate to treat psoriasis in a mammal, since Olsen et al. suggest that a pharmaceutically acceptable salt can be used to treat the same said conditions.

One having ordinary skill in the art would have been motivated to use the method suggested by Olsen et al. to administer a pharmaceutically acceptable salt of chondroitin sulfate such as sodium chondroitin sulfate to treat psoriasis in a mammal, since a skilled artisan would reasonable expect to use the composition taught by Olsen et al. for the same said purpose. It should be noted that the use of specific routes of administration such as topical or oral

administration depends on factors such as the severity and location of the psoriasis treated, the type, age and size of mammal. It should be noted that the use of sodium chondroitin sulfate of specific molecular weight and of specific dosage, amount or sulfur content depends on factors such as the severity of the psoriasis treated and the type, age and size of mammal.

Response to Arguments

Applicant's arguments with respect to claims 10-18 have been considered but are not found convincing.

The applicant argues that Olsen et al does not teach or suggest the use of chondroitin sulfate directly obtained from animal cartilage to treat psoriasis. However, it should be noted that the source of the chondroitin sulfate does not further limit the chondroitin sulfate used. That is, regardless of the source from which the chondroitin sulfate, both applicant and Olsen et al use or suggest the use of same compound, chrondroitin sulfate.

The applicant argues that Olsen et al does not describe a method of directly producing chondroitin sulfate from animal cartilage. Rather, Olsen et al teaches a method of producing chondrocytes from animal cartilage. Olsen et al may suggest obtaining chondroitin sulfate from said cultured chondrocytes, but does not describe a method for doing so. However, the instant claims are not drawn to a method of producing chondrocytes or chrondroitin sulfate and consequently the manner in which the chrondroitin sulfate is produced or obtained does not change or alter the fact that Olsen et al. suggest treating psoriasis in a mammal, comprising administering a pharmaceutically acceptable salt of chondroitin sulfate such as sodium chondroitin sulfate to said mammal.

The applicant argues that there is nothing in Olsen et al about the characteristics of the chondroitin sulfate obtained from said cultured chondrocytes, nor is there any scientific data which demonstrate the beneficial effect of the chondroitin sulfate obtained from the *in vitro* cultured chondrocytes for treating psoriasis, or for any of the other diseases mentioned in Olsen et al. Olsen et al does not disclose any study with Psoriatic Patients treated with chondroitin sulfate. Olsen et al does not disclose any clinical activity of chondroitin sulfate. Olsen et al only discloses a way to obtain anti-angiogenic fractions (see Example 2 of Olsen et al) and the activity of said fractions in an *in vitro* assay with cancer cell lines (see Example 3, page 30, lines 1-10, of Olsen et al). An *in vivo* assay with rats that had developed a breast cancer is also disclosed (see Example 3, page 30, lines 11-22, of Olsen et al). However, as set forth in the above rejection, Olsen et al. disclose that psoriasis in a mammal (human or animal) can be treated by administering to said mammal chondroitin sulfate (see claims 47 and 49; see also claims 1-5). Also, it should be noted that applicant's method does not claim or recite the use of chondroitin sulfate that has specific characteristics or specific beneficial effects.

The applicant argues that moreover, a skilled person in the art (an expert in the field of cellular cultures, as well as in the field of glycosaminglycans) knows that obtaining chondroitin sulfate by means of in vitro cultured chondrocytes would be non-viable from an industrial and economic point of view, due to the large amount of colonies of chondrocytes that would be required to isolate a small amount of chondroitin sulfate for use in the treatment of psoriasis. However, the instant claims are not drawn to a method of producing chondrocytes or chrondroitin sulfate and consequently the amount of chrodrotin produced in any particular method and manner in which the chrondroitin sulfate is produced or obtained does not change or

alter the fact that Olsen et al. suggest treating psoriasis in a mammal, comprising administering a pharmaceutically acceptable salt of chondroitin sulfate such as sodium chondroitin sulfate to said mammal. In addition, as set forth in the above rejection, Olsen et al. disclose that psoriasis in a mammal (human or animal) can be treated by administering to said mammal chondroitin sulfate (see claims 47 and 49; see also claims 1-5). Furthermore, it should be noted that the source of the chondroitin sulfate does not further limit the chondroitin sulfate used. That is, regardless of the source from which the chondroitin sulfate, both applicant and Olsen et al use or suggest the use of same compound, chrondroitin sulfate.

The applicant argues that the Examiner is requested to note that sodium chondroitin sulfate, which has an average molecular weight of between 10,000 and 40,000 daltons (Claim 13); and sodium chondroitin sulfate, which has an average molecular weight of between 10,000 and 20,000 daltons (Claim 14), are isolated from either bovine cartilage or pig cartilage. The preferred chondrocyte source in Olsen et al is elasmobranch cartilage (see Claim 3; page 7, line 6; and page 8, lines 11-12, of Olsen et al) ; and more specifically ray or shark chondrocytes (see Claim 5 of Olsen et al). The chondroitin sulfate obtained from ray or shark cartilage has an average molecular weight greater than 50,000 daltons (see for example Volpi, "Analytical Aspects of Pharmaceutical Grade Chondroitin Sulphates", *J. Pharm Sci.,*96:3168-3180 (2007); a copy of which is attached hereto). On the contrary however, Exhibit A (which is provided by the Examiner) discloses chondroitin sulfate of mean molecular weight of approximately 12,500 to 18,500 which has been obtained from chondrocytes cultures and which has the molecular weight range claimed by applicant (see Exhibit A, abstract).

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

April 18, 2008.

/Shaojia Anna Jiang, Ph.D./

Supervisory Patent Examiner, Art Unit 1623